

REMARKS

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims and the following remarks.

Status of the Claims

Claims 4-16 are now present in this application. Claims 4 and 10 are independent. Claims 6-12 stand withdrawn from consideration as being directed to non-elected subject matter.

Claims 1-3 were previously canceled. Claims 4, 5, 13 and 15 have been amended herein. Reconsideration of this application, as amended, is respectfully requested.

Claim Amendments

Applicants have amended the claims such that "X" is now a bromine atom (wherein this definition previously appeared in claim 5), and "R¹" is no longer "a substituted or unsubstituted C₁₋₆ alkyl." The amendments actually delete subject matter. Thus, Applicants submit that the amendments made herein are fully supported in the present specification as filed and add no new matter. Further, the amendments made herein address issues that are first raised in the outstanding Office Action, and were not made earlier, because the first indication to Applicants that the present amendments would be needed was in that Office Action. Therefore, though in response to a Final Office Action, entry of the present amendment is proper, and is respectfully requested.

Based upon the above considerations, entry of the present amendment is respectfully requested.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Examiner Interview

Applicant wishes to thank the Examiner for the courtesies extended to Applicant's representative during the interview which was conducted on March 9, 2010. During the interview, proposed changes to the claims were discussed in an attempt to overcome the prior art rejection of record. The claims have been amended in the manner discussed during the interview, and are believed to place the application into condition for allowance. Accordingly, reconsideration and allowance of the present application are respectfully requested.

Issues under 35 U.S.C. § 103(a)

Claims 4 and 15 rejected under 35 U.S.C. § 103(a) as being unpatentable in view of newly cited **Faust et al.** (*J. Med. Chem.*, Vol. 43, pp. 1050-1061 (2000)) (see pages 3-4 of the Office Action). Applicants respectfully traverse and reconsideration is based on the following remarks. Overall, Applicants do not concede that a *prima facie* case of obviousness has been established.

In the Office Action, the Examiner states that the only difference between the instantly claimed compound and that of Faust et al. is that R¹ of the present invention represents a substituted or unsubstituted C₁-C₆ alkyl and not a hydrogen atom (Office Action, page 3). Further, the Examiner states that the substitution of hydrogen with a substituted or unsubstituted C₁-C₆ alkyl is obvious because the substitution does not change the binding affinity or

stereochemistry of the compound (Office Action, top of page 4), with citation to *In re Norris*, 84 USPQ 458 (CCPA 1950) and *In re Finley*, 81 USPQ 383 (CCPA 1949).

Applicants respectfully refer the Examiner to claims 4 and 15 as shown herein. As recited in claim 4, X is now a bromine atom, and R¹ no longer represents “a substituted or unsubstituted C₁₋₆ alkyl”. Claim 15 depends on claim 4. Thus, there are several distinctions of the present invention over the cited Faust et al. reference.

Regarding definition (2) of claim 4, Applicants note that the cited compound of Faust et al. discloses R², R³, R⁵ and R⁶ as hydrogen atoms (Office Action, page 3). In this regard, R², R³ and R⁵ are different in the present invention.

Furthermore, compound “1b” of Faust et al. is 2-[¹²⁵I]iodomelatonin which is used in radioligand binding studies (at page 1051 of Faust et al.). The substitution of [¹²⁵I] with a “bromine atom” as instantly claimed cannot be obvious, especially given how Faust et al. is directed to a different objective.

Also, the disclosure at page 1051 of Faust et al. is merely background or exemplary (a part of the “Background” section), and that the article is directed to preparing derivatives of melatonin (see page 1052 and so forth). Further, based on disclosure of the derivatives in Faust et al., one of ordinary skill in the art has no reason or basis to make, e.g., a substitution at R¹ of a background compound as achieved by the present invention.

In addition, the instantly claimed compound of claim 14 has functions of activating osteoblasts and suppressing osteoclasts. Such a compound is useful for a pharmaceutical composition for various bone-related diseases, such as a pharmaceutical composition for preventing or treating osteoporosis, or as an osteoblast activator and an osteoclast suppressor, in

various fields, such as regenerative medicine, dentistry, or production of edible meats or eggs via fish cultivation or healthy development of livestock (see page 9, line 24 to page 10, line 2 and Example 15 of Applicants' specification). Such advantages are not disclosed in Faust et al.

MPEP § 2143 sets forth the guidelines in determining obviousness. First, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which has provided the controlling framework for an obviousness analysis. The four *Graham* factors of: determining the scope and content of the prior art; ascertaining the differences between the prior art and the claims that are at issue; resolving the level of ordinary skill in the pertinent art; and evaluating any evidence of secondary considerations. 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). Second, the Examiner has to provide some rationale for determining obviousness, wherein MPEP § 2143 set forth some rationales that were set established in the recent decision of *KSR International Co. v Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (U.S. 2007).

Applicants respectfully submit that the *Graham* factors weighs in Applicants' favor, and that a proper rationale has not been set forth in forming the outstanding rejections. For instance, Faust et al. does not disclose such advantages of the present invention (e.g., a pharmaceutical composition useful for various bone-related diseases, such as preventing or treating osteoporosis; etc.), and thus the *Graham* factors of ascertaining the differences between the prior art and the claims that are at issue and evaluation of any evidence of secondary considerations weigh in Applicants' favor. Also, there are several distinctions of the present invention versus the Faust et al. compound(s).

Accordingly, Applicants respectfully submit that the combination of elements as set forth in independent claim 4 is not disclosed or made obvious by the prior art of record for the reasons explained above. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

With regard to dependent claim 15, Applicants submit that this claim is allowable as well for the reasons set forth above.

Reconsideration and allowance of these two claims are respectfully requested.

Claim Objections

Claims 5 and 13-16 stand objected to as stated on page 2 of the Office Action. As these claims are not rejected in view of any prior art, it is believed that these claims would otherwise be allowable.

Withdrawn Claims

Applicants respectfully submit that the product claims are allowable as discussed. Because of this, reconsideration and rejoinder of at least claims 6-9 are respectfully requested in view of *In re Ochiai*, 37 USPQ2d 1127 (Fed. Cir. 1995). Applicants also note MPEP § 821.04(b).

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all

presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance.

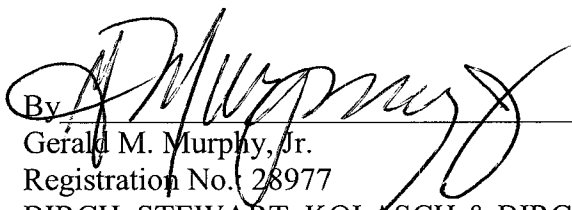
In view of the above amendment, Applicants believe the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eugene T. Perez, Registration No. 48501 at the telephone number of the undersigned below to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Director is hereby authorized in this, concurrent, and future replies to charge any fees required during the pendency of the above-identified application or credit any overpayment to Deposit Account No. 02-2448.

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Respectfully submitted,

By 
Gerald M. Murphy, Jr.
Registration No. 28977
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Road, Suite 100 East
P.O. Box 747
Falls Church, VA 22040-0747
703-205-8000